

**CREDENTIALING OF PERSONNEL
INVOLVED IN HUMAN SUBJECTS RESEARCH**

1. **PURPOSE:** To establish a service level policy that identifies the personnel involved in human subjects research that must have their credentials verified and the process for verifying such credentials consistent with VA policy. This policy assures that the education, certification(s) and license(s) of all personnel involved in human subjects research will be verified and files maintained to help assure personnel are appropriately educated, certified, and/or licensed to effectively and safely perform human research at the Portland VA Medical Center (PVAMC).
2. **POLICY:** Personnel involved in human subjects research at the PVAMC must have their credentials verified to ensure appropriate completion of stated education, certification(s) and license(s), prior to working on PVAMC IRB approved research projects. Participation on PVAMC IRB approved research projects is contingent upon successful completion of credentialing requirements.
3. **RESPONSIBILITIES:**
 - a. The **Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for:
 - (1) Completing credentialing requirements as defined by national and local policy.
 - (2) Developing and managing credentialing policies and procedures for personnel involved in human subjects research at the PVAMC.
 - (3) Ensuring all personnel involved in human subjects research at the PVAMC have completed the appropriate credentialing requirements consistent with VA policy.
 - b. The **Administrative Officer for Research & Development (AO/R&D)** is responsible for:
 - (1) Completing credentialing requirements as defined by national and local policy with the exception of the Scope of Work Form.
 - (2) Overseeing the Research Service staff involved with the credentialing of personnel involved in human subjects research.
 - c. The **Research and Development Committee (R&D) Members** are responsible for completing credentialing requirements with the exception of the Scope of Work Form.
 - d. The **Research and Development Committee (R&D) Coordinator** is responsible for completing credentialing requirements.
 - e. The **Institutional Review Board Members** are responsible for completing credentialing requirements with the exception of the Scope of Work Form.
 - f. The **Institutional Review Board Coordinators** are responsible for:
 - (1) Completing credentialing requirements as requested by the Research Service staff.
 - (2) Forwarding new research project proposals to the Research Assurance & Compliance Coordinator (RACC) to assure all personnel have successfully completed the credentialing requirements, prior to forwarding to the IRB for review.
 - (3) Only forwarding new research project proposals to the IRB for which the RACC has determined that all necessary staff have successfully completed the credentialing requirements.
 - g. The **Research Assurance and Compliance Coordinator** is responsible for:
 - (1) Validating the education, certification(s), and/or license(s) as reported on the Education Verification Form or VA Employee Application(s) for personnel involved in human subjects research at the PVAMC.
 - (2) Monitoring personnel compliance with the credentialing requirements.

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program: Policy & Procedure No. 10

Effective: 01/26/2004

- (3) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with credentialing requirements.
- (4) Reviewing monthly queries from the Department of Health & Human Services Office of the Inspector General, List of Excluded Individuals/Entities (LEIE) and verifying whether or not personnel participating on PVAMC IRB approved research projects from this list and the Food & Drug Administration Debarment List are present.
- (5) Maintaining the Human Subjects Research section of the Personnel Database.
- (6) Verifying annually that the license(s) and certification(s) of those individuals not in VetPro are still current and in good standing.

h. The Research Service Human Resources Liaison is responsible for:

- (1) Identifying, initiating, processing and following-up with personnel involved in human subjects research at the PVAMC required to have Without Compensation (WOC) appointments.
- (2) Monitoring personnel compliance with WOC appointments.
- (3) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with WOC requirements.
- (4) Working with Human Resources to ensure the WOC appointments are complete.
- (5) Maintaining updated WOC files.

i. Technical Information Specialist is responsible for:

- (1) Downloading monthly the Department of Health & Human Services Office of the Inspector General, List of Excluded Individuals/Entities (LEIE).
- (2) Forwarding the monthly report to the RACC for review.

j. Personnel involved with PVAMC IRB approved research projects are responsible for completing credentialing requirements as requested prior to participating on PVAMC IRB approved research projects.

4. PROCEDURES:

a. Personnel involved in PVAMC IRB approved human subjects research projects are required to complete the credentialing requirements. These individuals may include PVAMC employees (Title 5 and 38), Portland VA Research Foundation Employees, Oregon Health & Science University (OHSU) employees or otherwise. A flow diagram depicting an overview of the required information is included in Appendix A. Involvement in a human research project includes:

- (1) Research staff who interact with VA patients via telephone or in person;
- (2) Research staff who collect and analyze identifiable VA patient laboratory specimens or VA patient data;
- (3) Research staff who perform VA patient laboratory tests or work with identifiable VA patient data;
- (4) Research staff with a Without Compensation appointment;
- (5) Research Service staff, including: ACOS/R&D, AO/R&D, R&D Committee Coordinator, IRB Coordinators, and RACC; and
- (6) R&D Committee and IRB members.

b. Personnel involved in PVAMC IRB approved human subjects research projects that are NOT required to complete the credentialing requirements.

- (1) Members of the research team who are strictly administrative staff, e.g. receptionist, including any individuals that may have contact with a patient for scheduling purposes only.
- (2) People who are based at an affiliate or other outside institution, and who do not come to the VA or do not directly interact with VA research participants.
- (3) Co-investigators who do not do work at the VA. A VA researcher may collaborate with researchers from outside the VA, but the VA portion of the study is conducted at the VA with VA personnel. The outside people may be co-investigators on a VA study, and have their names listed on the

informed consent form(s) given to VA enrollees, but if the outside researchers do not come to the VA to perform the research or enroll VA patients.

- (4) Outside biostatisticians, e.g. VA researchers may send their data to an affiliate or other outside-based statistician for processing.
- (5) Outside lab technicians (e.g., VA researcher may send VA specimens to be processed at an affiliate or other outside lab).
- (6) Volunteers from the community who serve on an IRB or R&D Committee.
- (7) Members of groups like Data Safety Monitoring Boards (DSMB) who are recruited from non-VA institutions.
- (8) Clinical personnel who periodically perform tests on research patients as part of their routine jobs (e.g., x-ray, nuclear medicine, or medical laboratory technologists who occasionally perform a test on a research patient as part of their routine clinical duties). The credentials and qualifications of these individuals were validated when they were initially appointed as Federal employees.

c. Personnel credentialed in VetPro

- (1) VetPro is the national VA credentialing system. Physicians, nurse practitioners, and other personnel, whether Title 38 Employees, fee basis or consulting and attending, with positions that require a professional license to interact with patients in a supervised setting are credentialed through this system.
- (2) Personnel with a professional license necessary to interact with patients in a supervised setting that are typically entered into VetPro, consistent with the Medical Service Credentialing Office procedures, will be referred and credentialed through the VetPro system by the Medical Service Credentialing Office.
- (3) Personnel who have been previously credentialed through VetPro do not need to complete additional credentialing requirements outlined in this policy.

d. PVAMC Employees involved with PVAMC IRB approved human research projects

Exception: The employee is or will be credentialed through VetPro.

- (1) PVAMC employees must complete and submit the following to the Research Service as indicated on the checklist in Appendix B:
 - (a) Scope of Work form signed by the Supervisor/Principal Investigator;
 - (b) Education Verification Form for each degree, certification, or license earned; and
 - (c) Copy of Professional License (if required for interaction with patients in a supervised setting).
- (2) The Research Service will request the required information from Human Resources as detailed in Appendix C.
- (3) The Research Service will verify education and/or certification(s) declared.
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) A human subjects research credentialing file for the individual will be maintained by the Research Service.

e. PVARF Employees involved with PVAMC IRB approved human research projects

Exception: The employee is or will be credentialed through VetPro.

- (1) PVARF employee must complete and submit the following to the Research Service as indicated on the checklist in Appendix D:
 - (a) Scope of Work form signed by the Supervisor/Principal Investigator;
 - (b) Education Verification Form for each degree, certification, or license earned; and
 - (c) Copy of Professional License (if required for interaction with patients in a supervised setting).
- (2) PVARF employees whose length of employment exceeds 60 calendar days must also have a WOC appointment. PVARF employees must complete and submit the following to the Research Service:
 - (a) PVARF Application Form (if not already completed);
 - (b) Copy of Curriculum Vitae (if available); and
 - (c) Intellectual Property Agreement.

- The employee must also be finger printed by Human Resources Division.
- (3) The Research Service will verify education and/or certification(s) declared.
 - (4) The Scope of Work form will be signed by the ACOS/R&D.
 - (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

f. OHSU Residents involved with PVAMC IRB approved human research projects

- (1) OHSU Residents must complete and submit the following to the Research Service as indicated on the checklist in Appendix E:
 - (a) Scope of Work form signed by the Supervisor/Principal Investigator;
 - (b) OF 612 Form;
 - (c) Copy of Curriculum Vitae (if available); and
 - (d) Intellectual Property Agreement.
- (2) OHSU Residents who wish to have a WOC may be granted a WOC appointment. The WOC appointment will be processed through Human Resources Division. The resident must also be finger printed by Human Resources Division.
- (3) The Research Service will request a Resident/Trainee Credentials Verification Letter (RCVL) from the Medical Service Credentialing Office for each Resident.
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

g. OHSU Employees involved with PVAMC IRB approved human research projects

Exception: The employee is or will be credentialed through VetPro.

- (1) OHSU employees must complete and submit the following to the Research Service as indicated on the checklist in Appendix F:
 - (a) Scope of Work form signed by the Supervisor/Principal Investigator;
 - (b) Education Verification Form for each degree, certification, or license earned; and
 - (c) Copy of Professional License (if required for interaction with patients in a supervised setting).
- (2) OHSU employees that will be participating on a PVAMC IRB approved research project that exceeds 60 calendar days must also have a WOC appointment. The OHSU employee must complete and submit the following to the Research Service:
 - (a) OF 612 Form;
 - (b) Copy of Curriculum Vitae (if available); and
 - (c) Intellectual Property Agreement.

The employee must also be finger printed by Human Resources Division.
- (3) The Research Service will verify education, certification and/or any licenses declared.
- (4) The Scope of Work form will be signed by the ACOS/R&D.
- (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

h. Volunteers involved with PVAMC IRB approved human research projects

Exception: The volunteer is or will be credentialed through VetPro.

- (1) The Volunteer must complete and submit the following to the Research Service as indicated on the checklist in Appendix G:
 - (a) Scope of Work form signed by the Supervisor/Principal Investigator;
 - (b) Education Verification Form for each degree, certification, or license earned; and
 - (c) Copy of Professional License (if required for interaction with patients in a supervised setting)
- (2) Volunteers that will be participating on a PVAMC IRB approved research project for at least 60 calendar days must also have a WOC appointment. The Volunteer must complete and submit the following to the Research Service:
 - (a) OF 612 Form;

- (b) Copy of Curriculum Vitae (if available); and
 - (c) Intellectual Property Agreement.
- The volunteer must also be finger printed by Human Resources Division.
- (3) The Research Service will verify education and/or certification(s) declared.
 - (4) The Scope of Work form will be signed by the ACOS/R&D.
 - (5) All documentation will be maintained in a human subjects research credentialing file for the individual by the Research Service.

i. Education Verification

- (1) Attendance, education, and/or degrees earned as declared by personnel on the Education Verification Form will be verified at the primary source. A reasonable effort will be made by the Research Service to identify and verify earlier degrees, e.g. bachelors or masters degrees, if only more advanced degrees were initially reported by an individual.
- (2) Personnel who have not completed education or received a degree from a higher source of education than high school, shall have the Supervisor provide a written declaration that the individual is capable of performing the duties required of the position and declare that the individual has or will be trained appropriately.
- (3) Acceptable verification sources include:
 - (a) National Student Clearinghouse: www.degreeverify.com;
 - (b) AACRAO Enrollment Services: <https://www.aacraoes.com/Default.aspx>;
 - (c) Credentials, Inc.: www.degreechk.com; and
 - (d) Direct communication (via fax, telephone, e-mail, transcript, website, etc.) with the education institution or the appropriate record retention warehouse.
- (4) Two attempts will be made to verify each education component identified on the Education Verification Form or VA application. If these two attempts are unsuccessful, a good faith effort has been made consistent with VA guidelines.
- (5) Written documentation of verification(s) should be received. If written documentation is or may not be obtained in a reasonable time frame, verbal verification is appropriate.
- (6) All attempts of education verification will be filed appropriately in the personnel's human subjects research credentialing file.

j. License/Certification Verification

- (1) Personnel that declare a professional license required for interaction with patients in a supervised setting will have the license and/or certification verified.
- (2) Acceptable verification sources include:
 - (a) State Board or licensure/certification websites and
 - (b) Direct communication (via fax, telephone, e-mail, website, etc.) with the licensing or certifying institution or the appropriate record retention warehouse.
- (3) Only those license(s) that are currently active will be verified. Only certifications that directly relate to human studies research and are currently active or have been received in the year prior to involvement with human studies research at the PVAMC will be verified.
- (4) Verification of license(s) and certifications will be filed appropriately in the personnel's human subjects research credentialing file.

k. Without Compensation (WOC) Appointments

- (1) Individuals who are not PVAMC employees and are working on PVAMC IRB approved research projects that exceeds 60 days must have a WOC appointment.
- (2) The WOC appointment may be through the Research Service or other service if more appropriate.
- (3) The Research Service will initiate and follow-up on the status of the WOC appointment for individuals requiring a WOC appointment through the Research Service.

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program: Policy & Procedure No. 10

Effective: 01/26/2004

l. Background Investigations

Individuals involved in human subjects research must have background investigations that are related to the risk level of their position. This is part of the normal VA hiring process. The Research Service will adhere to the Human Resources Division policies for background investigations, consistent with VA policy.

- (1) VA employees have a full background investigation.
- (2) All individuals with a WOC appointment must be fingerprinted. If the results of the fingerprinting are questionable, a full background investigation must be completed.

m. Exclusionary Lists

- (1) Individuals involved in human subjects research will be verified against the following exclusionary lists monthly:

- (a) Department of Health & Human Services Office of the Inspector General, List of Excluded Individuals/Entities (LEIE) List:

- <http://www.oig.hhs.gov/fraud/exclusions/listofexcluded.html> and

- (b) Food & Drug Administration Debarment List: http://www.fda.gov/ora/compliance_ref/debar/.

- (2) In the event an individual appears on either exclusionary list, the AO/R&D and ACOS/R&D will be notified immediately. Appropriate action will be taken with consultation from Human Resources Division.

n. Record Retention

Human subjects research credentialing files will be maintained for six years after the termination date of the appointment.

5. REFERENCES: Credentialing of Personnel Involved in Human Subjects Research Memorandum from the Deputy Under Secretary for Health Operations and Management
VHA Handbook 0710, Personnel and National Information Security, October 30, 2000

6. CONCURRENCES: Endorsed by the Research & Development Committee on 01/26/2004.

7. RESCISSION: None

8. FOLLOW-UP RESPONSIBILITY: ACOS, R&D Service

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service